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Applications of spray drying and spray congealing to improve poorly water soluble drug dissolution

A. A. Elkordy¹, E. Essa², A. M. Faheem³

¹ Faculty of Applied Sciences, Department of Pharmacy, University of Sunderland, Sunderland, UK, ² Faculty of Pharmacy, Department of Pharmaceutical Technology, University of Tanta, Tanta, Egypt, ³ School of Biomedical Sciences, Department of Pharmacy, University of Ulster, Coleraine, UK

Purpose.

To enhance the dissolution of ibuprofen, a model poorly water soluble drug, via spray drying and spray congealing technologies.

Methods.

Drug particles were formulated in absence and presence of a hydrophilic surfactant, poloxamer 407 (1:1w/w drug:surfactant) by: (i) spray drying with 40:60 ethanol:water as a solvent and (ii) spray congealing by melting the components at 90°C using Mini Spray Dryer B-290. Formulations were evaluated using drug content analysis, dissolution testing, scanning electron microscopy (SEM), FT-IR spectroscopy and differential scanning calorimetry (DSC).

Results.

Spray drying and spray congealing of ibuprofen with poloxamer 407 produced formulations with uniform drug distribution. Spray dried products containing poloxamer 407 better enhanced ibuprofen dissolution compared to pure and spray congealed drug. A burst release was observed after 5 minutes of 100mg drug release, 82 ± 1.1 , 90 ± 0.2 , 21 ± 2.6 , 38 ± 1.7 and $36\pm0.6\%$ of ibuprofen released from spray dried drug, spray dried drug with surfactant, spray congealed drug, spray congealed drug with surfactant and pure drug, respectively. Spray drying produced amorphous materials which resulted in faster dissolution rate compared to started crystalline material; this was confirmed by DSC data. Poloxamer 407 improved the wetting ability of drug particles and this prevented aggregation and increased surface area of particles when exposed to aqueous dissolution medium. This also could explain the burst drug release of spray dried products in the presence of surfactant. The low dissolution rate for drug particles prepared by spray congealing may be explained by: (i) formation of strong melt-solidified bonds and (ii) formation of a new polymorph as demonstrated by DSC (there were two endothermic peaks) and FT-IR (appearance of a new peak at 1548 cm^{-1}) results. SEM of pure ibuprofen exhibited drug crystalline structure. Whilst, SEM of spray dried ibuprofen with and without surfactant showed particles with irregular porous surface, the surface of spray congealed particles was nonporous and wrinkled.

Conclusion.

Spray drying of ibuprofen with or without poloxamer 407 significantly enhanced drug dissolution rate compared with pure drug. Spray congealing showed formation of a new polymorph. This polymorph was responsible for poor dissolution of spray congealed drug.